

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION**

GRAND RIVER ENTERPRISES SIX
NATIONS, LTD.,

Plaintiff,

v.

AUSTIN KNUDSEN, in his official
capacity, Attorney General of the State of
Montana,

Defendant.

CV-23-48-GF-BMM

ORDER

INTRODUCTION

Defendant Austin Knudsen, in his official capacity as the Attorney General of the state of Montana (the “Attorney General”) filed a motion for summary judgment on April 26, 2024. (Doc. 73.) Plaintiff Grand River Enterprises Six Nations, Ltd. (“GRE”) opposes the Attorney General’s motion. (Doc. 87.) GRE filed a cross motion for summary judgment on May 1, 2024. (Doc. 78). The Attorney General opposes GRE’s motion. (Doc. 90). GRE filed a motion in limine on May 8, 2024. (Doc. 82.) The Attorney General opposes GRE’s motion in limine. (Doc. 99.) The Court conducted a motion hearing on June 17, 2024. (Doc. 102.)

FACTUAL AND LEGAL BACKGROUND

The facts remain the same as those presented in the Court’s previous orders. (Doc. 21); (Doc. 40); (Doc. 65.) Montana law requires the Attorney General to maintain a directory (the “Montana Tobacco Directory”) of tobacco products sold in the state. The Montana Tobacco Directory lists “all tobacco product manufacturers that have provided current and accurate certifications conforming to [specific requirements] and all brand families that are listed in the certifications.” Mont. Code Ann. § 16-11-504. Montana has established a process for each tobacco product manufacturer to obtain an annual certification that allows for the sale of its products within the state. *See* Mont. Code Ann. § 16-11-503. Tobacco product manufacturers must complete the certification and remain included in the Montana Tobacco Directory to sell their products.

A. Assurance of Voluntary Compliance.

GRE participated in the Montana tobacco market pursuant to an Assurance of Voluntary Compliance agreement (“AVC”) it entered with the State in 2012. (Doc. 8-1.) The State does not require compliance agreements for every cigarette manufacturer operating in Montana. (*Id.*) GRE sought through the AVC to “come into compliance with the laws of the State of Montana and to be listed on the [Montana Tobacco Directory] as a non-participating manufacturer whose cigarettes are approved for sale in the State of Montana.” (*Id.* at 3.)

The AVC requires GRE to comply with specific terms to sell its products in Montana. (*Id.*) The AVC's mandates include the requirement that GRE comply with "all local, state, and federal laws." (*Id.* at 4.) The AVC further provides that "failure to abide by any terms of this AVC is grounds for the immediate removal of [GRE] from the Montana [Tobacco] Directory." (*Id.*) The AVC finally states that "[t]he parties acknowledge and agree that this AVC is voluntarily entered into by the parties as a result of arm's-length negotiations and that the parties each had the opportunity to review this matter with counsel prior to executing this AVC." (*Id.* at 5.)

B. Attorney General's Letter to GRE.

The Attorney General sent GRE a letter on May 9, 2022, in which the Attorney General alleged that GRE had withdrawn eight tobacco brand styles from FDA substantial equivalence review in January 2020. (Doc. 8-2 at 1-4.) The FDA had deemed the eight brand styles adulterated and misbranded due to GRE's withdrawal and prohibited GRE from distributing, importing, selling, marketing, or promoting these eight styles. (Doc. 8-2); (Doc. 8-9 at 8, 30.) The Attorney General further alleged that GRE knowingly had included these eight brand styles in its 2020 and 2021 Montana Tobacco Directory certifications despite the FDA's determination that the eight brand styles had been deemed adulterated. (Doc. 8-2 at 2-4.) The Attorney General accused GRE of having failed to update their Montana tobacco

product manufacturer certifications based on the FDA’s determination, and, as a result, GRE listed such brands on the Montana Tobacco Directory “knowing that the brand was adulterated and misbranded under federal law.” (*Id.* at 2.)

The Attorney General viewed GRE’s conduct as having violated federal law. (*Id.*) The Attorney General also characterized GRE’s conduct as violating Montana law through GRE’s failure to update its tobacco product manufacturer (“TPM”) certifications to remove the eight brand styles. (*Id.* at 3.) The Attorney General further asserted that GRE may have violated the AVC’s requirement that GRE remain in compliance with all local, state, and federal laws. (*Id.*) The Attorney General’s letter informed GRE that the eight brand styles would be removed from the Montana Tobacco Directory and that the Attorney General considered the removal an “enforcement action.” (Doc. 7 at 3); (Doc. 8-2 at 4.)

GRE responded to the Attorney General’s initial letter on May 26, 2022. (Doc. 7 at 3.) GRE confirmed to the Attorney General that it had requested that the FDA withdraw the eight brand styles from review in January 2020. (*Id.* at 3-4.) GRE asserted that it did not object to removing the eight brand styles from the 2022 Montana Tobacco Directory. The 2022 Montana Tobacco Directory included all of GRE’s products except the eight brand styles referenced in the Attorney General’s letter. (*Id.* at 4.)

C. The Attorney General's Removal of GRE.

The Attorney General subsequently sent GRE a letter on June 14, 2023, informing it that the Attorney General had sent all Montana wholesalers a "Notice of Intent to Remove," in which it notified Montana wholesalers that they were prohibited from selling GRE products if the products had been shipped to wholesalers after June 14, 2023. (*Id.* at 4); (Doc. 8-9 at 1.) The letter also informed GRE that the Attorney General would remove all of GRE's products from the Montana Tobacco Directory on July 14, 2023. (Doc. 7 at 4); (Doc. 8-9 at 1-3.)

D. GRE's Motion, Appeal, and Related State Court Proceedings.

The procedural posture of this action proves lengthy. GRE filed its motion for a temporary restraining order, order to show cause, and order for a preliminary injunction on July 10, 2023. (Doc. 6.) The Court denied GRE's motion for a temporary restraining order and stayed consideration of GRE's motion for a preliminary injunction on July 17, 2023. (Doc. 21.) GRE filed an interlocutory appeal with the Ninth Circuit on July 20, 2023. (Doc. 22.) GRE subsequently filed an emergency motion for an injunction on July 24, 2023. (Doc. 26.) GRE filed additionally a motion for reconsideration on August 4, 2023. (Doc. 31.) The Court denied GRE's emergency motion for an injunction and stayed consideration of GRE's motion for reconsideration on September 1, 2023. (Doc. 40.)

The Ninth Circuit ordered the Court to consider GRE's motion for reconsideration on September 11, 2023. (Doc. 42.) The Court denied GRE's motion for reconsideration on September 18, 2023. (Doc. 44.) GRE filed a motion to clarify and a request for an indicative ruling on November 21, 2023. (Doc. 56.) The Court granted GRE's motion to clarify and request for an indicative ruling on December 11, 2023. (Doc. 63.) The Court determined that it would deny GRE's motion for a preliminary injunction on the same grounds stated in the Court's order denying GRE's emergency motion for an injunction pending appeal. (*Id.* at 5.) The Ninth Circuit remanded this action to the Court for the sole purpose of considering GRE's motion for a preliminary injunction on January 11, 2024. (Doc. 64.) The Court subsequently denied GRE's motion for a preliminary injunction on January 12, 2024. (Doc. 65.) GRE filed a notice of interlocutory appeal on January 16, 2024. (Doc. 66.)

The Ninth Circuit reversed the Court's denial of GRE's motion for a preliminary injunction on June 14, 2024. (Doc. 100.) The Ninth Circuit determined that GRE likely would succeed on the merits of its preemption claim because the Attorney General predicated the removal of GRE from the Montana Tobacco Directory on a purported violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"). (*Id.* at 3-4.) The Ninth Circuit further noted that federal law preempts state law claims that exist solely by virtue of the FDCA. (*Id.* at 5.) This federal

preemption includes attempted enforcement of the AVC in the current instance. (*Id.*) The Ninth Circuit remanded this matter to the Court for further proceedings. GRE filed a proposed order granting a preliminary injunction on June 20, 2024. (Doc. 105). The Attorney General objects to GRE's proposed preliminary injunction and filed his own proposed preliminary injunction motion on June 21, 2024. (Doc. 106.)

The Montana District Court, First Judicial District, Lewis and Clark County, denied GRE's motion for a preliminary injunction in the parallel state proceeding *In the Matter of Grand River Enterprises, Inc.*, Cause No. ADV-2012-246 (Oct. 3, 2023). The Montana state district court determined that the AVC granted the Attorney General the authority to remove GRE from the Montana Tobacco Directory upon a violation of the AVC. The Montana state district court left unanswered the issue of whether the Attorney General's basis for removing GRE from the Montana Tobacco Directory relied upon an alleged violation of federal law by GRE.

LEGAL STANDARD

Fed R. Civ. P. 56 provides that a court shall grant summary judgment if the moving party demonstrates that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Material facts are those that may affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The party moving for summary judgment bears the burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v.*

Catrett, 477 U.S. 317, 323 (1986). If the moving party meets its initial responsibility, the burden then shifts to the opposing party to establish that a genuine issue as to any material fact exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The Court must view all inferences drawn from the underlying facts in the light most favorable to the non-moving party when making this determination. *See id.* at 587.

Cross-motions for summary judgment do not require a court to grant one of the motions. A court still must determine whether summary judgment proves appropriate for either party. *Fair Housing Council of Riverside County, Inc. v. Riverside Two*, 249 F.3d 1132, 1136 (9th Cir. 2001). District courts maintain the discretion to deny summary judgment where justice and fairness require a trial on the merits. *See Anderson*, 477 U.S. at 255.

DISCUSSION

The Court will consider first the parties' cross-motions for summary judgment. The Court need not consider GRE's motion in limine or the parties' proposed preliminary injunctions because the Court determines that summary judgment proves appropriate for GRE.

A. The parties' motions for summary judgment.

GRE broadly asserts two grounds in its motion for summary judgment: 1) federal law preempts the Attorney General's basis for removal; and 2) the Attorney

General violated GRE's due process rights when he unilaterally removed GRE from the Montana Tobacco Directory. The Court need not reach the due process issue. The Court agrees that federal law preempts the Attorney General's basis for removal pursuant to the AVC.

The parties agree that all pertinent facts have been established. The Attorney General's June 14, 2023 notice of removal letter provides in relevant part: "GRE, *inter alia*, marketed and promoted adulterated and misbranded cigarettes on the [Tobacco] Directory for sale in Montana *in violation of federal law*." (Doc. 86-8 at 2) (emphasis added). The Attorney General further wrote "GRE, *inter alia*, marketed and promoted on the [Tobacco] Directory to the Montana public cigarettes that it knew to be adulterated and misbranded for over two years *in violation of federal law*." (*Id.* at 3) (emphasis added). The Attorney General concluded that "GRE's actions constituted a violation of the 2012 AVC and the Attorney General's Office is exercising its right to immediately remove GRE from the [Montana Tobacco] [D]irectory." (*Id.* at 4.)

The Court determines that federal law preempts the Attorney General's removal of GRE based on a purported violation of the FDCA. The FDCA implicitly preempts state law claims based solely on a violation of the FDCA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352–53 (2001). An action for a violation of state law "may not be pursued when . . . the [action] would require

litigation of the alleged FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation.” *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1049 (9th Cir. 2022) (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010.)) The FDA remains responsible for investigating potential FDCA violations. The FDCA empowers the FDA to employ a range of enforcement mechanisms including injunctive proceedings and civil and criminal penalties. *See* 21 U.S.C. §§ 332–34, 372; *see also* *Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013). The FDCA speaks in no uncertain terms concerning enforcement power: “. . . all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States,” subject to certain, limited exceptions. 21 U.S.C. § 337(a).

The Attorney General predicated GRE’s removal from the Montana Tobacco Directory on an underlying violation of the FDCA. The parties disagree as to whether GRE violated the FDCA when it listed the eight adulterated brand styles on its 2020 and 2021 Montana Tobacco Directory certifications after GRE had removed these eight brand styles from FDA substantial equivalence review. *Cf.* (Doc. 80 at 23-26); (Doc. 74 at 7-8.) The Attorney General presents no evidence that the FDA determined that GRE had violated the FDCA by having listed the eight adulterated brand styles on GRE’s 2020 and 2021 TPM certifications. The adjudication of whether GRE’s continued listing of the eight adulterated brand styles in 2020 and

2021 violated the FDCA would require the litigation of the alleged FDCA violation in the absence of FDA enforcement. *See Nexus Pharms.*, 48 F.4th at 1049. The broad language of the FDCA preempts precisely this type of claim. *Id.*

The Court agrees with the Montana state district court that the AVC grants the Attorney General the authority to remove GRE from the Montana Tobacco Directory. The AVC's plain terms reveal as much: "failure to abide by any terms of this AVC is grounds for the immediate removal of [GRE] from the Montana [Tobacco] Directory." (Doc. 8-1 at 4.) Federal law preempts the Attorney General's removal of GRE from the Montana Tobacco Directory in this instance, however, because an alleged violation of the FDCA served as the basis for the removal when the FDCA provides no private right of action. The Attorney General's *post hoc* justification that GRE was removed from the Montana Tobacco Directory for violating state law and the AVC proves unavailing when the Attorney General's July 14, 2023 notice of removal letter lists only a violation of federal law as the basis for GRE's removal. (*See* Doc. 86-8 at 2-4.)

The Court determines narrowly that the Attorney General's June 14, 2023 removal letter proves to be a preempted enforcement of the FDCA where the FDA itself had not concluded the existence of a violation. *See Nexus Pharms.*, 48 F.4th at 1049; *see also* (Doc. 100 at 4.) The Court agrees with the Montana state district court that a failure by GRE to comply with other local, state, or federal laws may provide

a basis for the Attorney General to remove GRE from the Montana Tobacco Directory pursuant to the AVC. The Attorney General has presented no other bases for removal to the Court at this time.

ORDER

Accordingly, **IT IS ORDERED:**

1. GRE's motion for summary judgment (Doc. 78) is **GRANTED**.
2. The Attorney General's motion for summary judgement (Doc. 73) is **DENIED**.
3. GRE's motion in limine (Doc. 82) is **DENIED** as moot.
4. The Clerk shall enter judgment in favor of GRE.
5. The Montana Attorney General is prohibited from enforcing his June 14, 2023 decision to remove GRE from the Montana Tobacco Directory based on a purported violation of the FDCA.
6. The Montana Attorney General will be ordered to re-list GRE on the Montana Tobacco Directory if GRE certifies its compliance with all other relevant Montana Tobacco Directory laws and its compliance with the AVC.
7. The Montana Attorney General will be ordered to retract its "Notice of Intent to Remove" GRE, and to inform Montana wholesalers and retailers that they can purchase GRE tobacco products. The Montana Attorney General will be ordered to take these steps if GRE follows all of the

requirements of the AVC and gets re-listed to the Montana Tobacco Directory.

8. Each party shall bear their own fees and costs.

DATED this 28th day of June 2024.

A handwritten signature in blue ink, reading "Brian Morris".

Brian Morris, Chief District Judge
United States District Court